

## **Case Report Forms by PharmaForms**

### **Automated Production**

The aim of clinical research is the quick, reliable generation and documentation of data. Errors at any part of the process chain lead to added costs. PharmaForms helps you minimise needless costs by optimising the all-important printing.

We automate the process through electronic printing and collating. Media breaks and human error are eliminated, and you get a final product that is exactly how you ordered it. We guarantee the quality of both printing and collating due to computer controlled processes.

We can do this because we print on high-volume electronic presses that are specifically configured for the production of Case Report Forms. The machines print and sort your documentation in a single production step, no matter how many different materials are involved.

All processes are designed to allow a seamless workflow.

### **Bookwise Printing**

Bookwise printing with electronic presses outperforms traditional offset printing in many ways. It is much faster, and the bookwise printing facilities at PharmaForms can print and collate all of the materials in your document in a single production step: paper in different colours, grammatures and sizes, dividers with and without tabs, all coated papers in your NCR sets, labels, faxesheets, ToCs, guidelines etc.

After electronic printing and collating, the stack of materials ("book", i.e. your document) is not disassembled manually for any reason, so there is no risk of misallocated or missing pages due to human error.

## **On-Demand Printing**

Do you hold a reserve quantity of CRFs per study besides the quantity of patients planned for recruitment? Do you want to start with a small number of CRFs at the beginning to see how your trial evolves and then extend the quantity when you have better information? Would you like to include your changes and amendments directly into reprints instead of changing pages manually?

On-demand printing is just that - printing when you need it, including small quantities. Our workflow is designed so that complete books are produced sequentially. This has important advantages for you:

We don't wait until the last page of the last book is printed before starting finishing of the first book. Upon receiving your order we immediately start to print, collate, finish and ship the most urgently needed quantity of CRFs.

## **Individualisation**

A core element of electronic printing technology is the absence of plates for printing identical pages. This absence is a good thing - it means that each page is sent to the press digitally and individually, which opens up the possibility of individualising each page.

You need a document with variable texts like multilingual patient diaries or with the investigator's individual name preprinted onto the document? Easy! You need a document with incremental barcodes at the page level? No problem! You need a submission dossier with 20,000 unique pages? Give us a call!

Individuality of each and every printed page is the feature of the technology used. It is nothing specially added on second machines. Make use of our technology. Make use of individualisation on page level for a smart trial organisation.

## Pharmaceutical Insight

PharmaForms was founded as a direct response to the needs of the pharmaceutical industry. Study managers and Research Assistants called for a new way to produce Case Report Forms, Patient Diaries and other documents.

Working with people from data management departments, we designed a workflow that meets the specific requirements of the clinical trial business. This includes barcoding, just-in-time delivery, worldwide shipment to investigative sites, quality-assured production, on-demand printing, online shipment tracking, smart random envelopes etc.

Our familiarity with the clinical trial process has generated many innovations and improvements that are appreciated by our customers all over the globe. And the innovative spirit at PharmaForms will continue to help optimise document processes.

We belong to several international organisations, and you can find us at the important conferences and trade shows.

To make it short: we are talking pharmaceutical.

## Worldwide Shipment

Once the CRF is ordered, proofed and printed, we strongly recommend letting us handle shipping the CRFs to the investigative site. We ship by DHL from our plant to wherever your investigator is based, be it Moscow, Seattle, Málaga or Buenos Aires.

As a customer, you can track shipments online on our [website](#) and see the current location of the package. You can trace who received the packages at what time, and check whether customs complications make your corpus arrive later.

Our customers appreciate the planning security this tool gives them. Check out our tracking demo by clicking [here](#) .

By the way: providing different sizes and binders with 4- or 3-ring mechanisms for the EU and the US respectively is a normal routine and daily business.

## **Barcoded Case Report Forms**

### **Barcode Benefits**

Time is money - a platitude, perhaps, but nowhere truer than in the pharmaceutical industry. With a barcoded CRF you can streamline your workflow and speed up processes.

Here's how it works: Each data-sheet of each book gets an individual barcode with information on the study number, the book number, the page number etc. Feel free to encode visit sections, centre numbers, countrykeys etc. When the form is completed, the CRF is scanned. Thanks to the barcode the scanned page is indexed automatically (no manual indexing necessary) and is so very well prepared for electronic archiving and submission.

Your benefits:

- Significant time gain
- More secure data transfer
- Automatic digital archiving and tracking
- Direct integration into eCTD

### **Track-And-Trace**

As soon as the CRF page is scanned, the CRF tracking program (available from different vendors, ask us for recommendations and contacts) reads the page, identifies its barcode and archives the digital page by the code information. The page can then be processed as you wish, in accordance with your workflow:

The study manager can be informed about the ongoing process of the study. A copy can be sent to the monitor for instant checking and eventual queries. The approved copy can be e-mailed to data entry workers anywhere - Munich, Bombay, Barcelona, you name it.

The barcode makes each page unique and supports tracking and tracing even in huge series of documents and over extended periods of time.

## Labels

Clinical trials rely both on interviews and on samples of our body fluids. Tubes have to be labelled for unambiguous identification of the source. Further documents result from investigation, such as medical reports and findings, ECG prints, doctor's letter etc.

For comfortable labelling, we offer the integration of labels into the CRF. The placement of these labels can vary according your preferences: they can be located on special "label sheets" at the end of the CRF, or integrated on the CRF page the investor has opened.

Sometimes, labels have to adhere to test tubes of different shapes and sizes, and adhesion must be centrifuge-resistant, temperature-resistant and shockproof. For this crucial element we rely on the extensive experience of our mother company Diagramm Halbach, with their specialised knowledge of critical label applications.

Labels are generally white. The investigator individualises them by writing the patient's name on it. However, for more sophisticated and optimised trial workflow we recommend label barcoding. Each label is coded for the specific subject and sample specification, and can easily be assigned to the right subject. Of course, barcode is just one possible solution, and sometimes plain writing is preferable - whichever the case, we do it your way.

## Experience

PharmaForms has provided many sponsors with barcoded CRF. Our CRFs are fully compliant with the requirements of CRF tracing and tracking systems solution providers with whom we work closely. This compliance is assured through first grade readability of the barcode, correct positioning and the use of the right symbology.

A highly sophisticated print and code administration installed into PharmaForms' workflow guarantees correctness of all printed codes. Computer aided checks avoid doublets of numbers, failures in symbology or restrictions in fax-collect systems. These checks are implemented on our site for smooth running of barcodes at your site.

A plain writing line below the barcode translates the barcode's content for the human eye. Please ask us for details on the appropriate symbology for your specific application, partner recommendations, CRF design issues and further recommendations.

## **Quality Assurance**

### **Philosophy**

"Precision in paper" is our motto at PharmaForms. It is our stated philosophy, but it is much more besides. It is reflected in the way we interact with our vendors, customers and employees, and last but certainly not least in the final product. For many years our workflow has been ISO 9001 compliant.

Our customers' responses reassure us that our quick and reliable quality meets the requirements of the clinical trial business.

Quality checks start in our own in-house laboratory, where all materials are tested and proofed for smooth running in presses and applications.

### **Closed Files**

To eliminate the danger of unintentional data modification through format conversion in our art department, we accept only closed files (principally PDF or PS). You can download everything you need to generate these formats [here](#) .

This facilitates proofreading as well, because it restricts this crucial element to a check of the materials used during the production and never to the integrity of the data itself. This saves time. It allows us to communicate with customers worldwide without any data hassle.

### **Permanent Checks**

Each production step is monitored according to a strict system of checks and proofs. Job managers can trace the documentation of executed checks and approvals by our controllers online.

Our staff is trained and conscious about the special requirements in clinical research documentation. The "4-eyes-principle" is rigorously respected at each control.

We at PharmaForms believe quality to be a value in itself. Moreover, it fulfils the important function of minimising queries in your document flow, and consequently the avoidance of additional costs.

Pharma**Forms** GmbH – Am Winkelstueck 14 – 58239 Schwerte / Germany  
Tel: +49/ 2304/ 7 59 59 - [info@pharmaforms.com](mailto:info@pharmaforms.com) - [www.pharmaforms.com](http://www.pharmaforms.com)

Finally, our goods are shipped to their investigative site by a carrier that has proved to be optimal for our needs: absolutely reliable and economical at

the same time. Through the online shipment tracking tool we provide here, you can keep tabs on how shipment proceeds. This keeps you in the loop at all times.